UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

GENENTECH, INC., Plaintiff, v. THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, a Pennsylvania non-profit corporation, Defendant.	Case No.: 10-CV-02037-LHK ORDER GRANTING PLAINTIFF LEAVE TO AMEND

Plaintiff Genentech, Inc. (Genentech) has moved to amend its complaint and answer to assert a claim for declaratory judgment of unenforceability and an additional affirmative defense based on allegations of inequitable conduct (Motion, Dkt. No. 163).[1] Genentech's proposed amendments assert that defendant Trustees of the University of Pennsylvania (U Penn) committed inequitable conduct while prosecuting U.S. Patent No. 6,733,752 (the '752 Patent). U Penn opposed the motion, and Genentech filed a reply brief. U Penn moved for leave to file a sur-reply to Genentech's reply on May 6, 2011. Genentech opposed U Penn's request for leave, and in the alternative asked for leave to file a sur-sur-reply on May 9, 2011.[2]

[1] Genentech has submitted both a proposed First Amended Complaint (FAC) as well as a proposed First Amended Answer. Because the inequitable conduct allegations in the two proposed amended pleadings are the same, this Order refers only to the FAC.

[2] The Court has reviewed the sur-reply and sur-sur-reply, and does not believe the sur-reply brief was warranted by new argument or evidence in Genentech's Reply. However, the sur-reply contains statements and admissions helpful to the analysis here. As a result, the Court GRANTS U

I. Introduction

Genentech seeks to add claims of inequitable conduct based on three alleged misrepresentations to the Patent and Trademark Office (PTO). First, Genentech argues that the inventors of the '752 Patent misrepresented how many mice survived for 90 weeks without tumors in the experiment disclosed in Example 2 of the '752 Patent. Second, Genentech argues that the inventors falsely stated that the claimed invention worked by down regulation, despite being aware that their research had been criticized for failing to show down regulation. Third, Genentech argues that one of the attorneys who prosecuted the '752 Patent falsely represented to the patent office that the application which became the '752 Patent (the '800 Application) was not abandoned at the time the PTO began re-examining the '800 Application.

a. First Alleged Misrepresentation

Genentech alleges that the inventors of the '752 Patent, Drs. Greene and Katsumata, misrepresented experimental results in the '752 Patent. The '752 Patent claims a method of "inhibiting development into breast cancer cells of breast cells" using antibodies. '752 Patent, claim 1. In Example 2, the '752 Patent describes an experiment performed on transgenic mice. The transgenic mice had been modified to develop breast tumors "between 20 and 45 weeks." '752 Patent 7:15-18. These mice were treated with the claimed antibodies every other week (the "low dose" treatment group) or twice a week (the "high dose" treatment group). '752 Patent 7:51-65. Six out of 12 mice in the high dose treatment group were reported to remain "free of tumors at more than 90 weeks of age." '752 Patent 7:65-8:5. The '752 Patent specification states that "this experiment indicates that treatment of transgenic mice with [the claimed antibody] twice weekly can effectively suppress tumor development in a large fraction of these mice for almost their entire life span (about 100 weeks). *Id.*

Genentech sought evidence of U Penn's conception and reduction to practice of the invention described in the '752 Patent, and U Penn responded by citing datasheets containing data from mouse experiments. FAC ¶ 44. Genentech cites these datasheets and alleges that they reveal

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Penn's request for leave to file the sur-reply, and Genentech's request for leave to file the sur-sur-reply. However, in the future, the parties are urged not to file additional briefing.

that the '752 Patent inventors misrepresented the results of the "high-dose" treatment group. FAC ¶ 42. Specifically, Genentech alleges that the data do not show that all six mice survived 90 weeks without tumors.[3] FAC ¶ 43. Rather, the data show that only two mice lived to 83 and 86 weeks without tumors. The remaining four mice died earlier than 83 weeks. FAC ¶¶ 44-45. Genentech alleges that this information was material to patentability because the inventors relied on the data to support their pending claims multiple times during prosecution, and because this experiment was the only data in the '752 patent demonstrating enablement. FAC ¶¶ 49, 52-58. Genentech alleges that a reasonable examiner would have relied on the misrepresented data to determine the patentability of claim 1 of the '752 Patent, and would have found the true data material to determining patentability. FAC ¶¶ 50-51.

b. Second Alleged Misrepresentation

Claim 1 of the '752 Patent claims a method of inhibiting the development of breast cancer using an antibody that binds to p185 "in sufficient amount to down regulate the overexpressed p185." '752 Patent Claim 1. Genentech alleges that the inventors knew that the experimental data cited in the '752 Patent did *not* demonstrate down regulation or support the addition of the "down regulation" requirement, and their contrary arguments to the PTO were therefore false and misleading. FAC ¶¶ 65, 94-96. Specifically, these alleged misrepresentations were made to overcome an enablement rejection, where the examiner found that "[t]he specification [does] not disclose *how* binding of the claimed antibodies to p185of normal cells in humans could prevent transformation from normal cells to tumor cells . . . ." FAC ¶ 60. In response to this rejection, U Penn added the "down regulation" limitation and argued that it was supported by the data in the patent. FAC ¶¶ 61-63. As evidence of the inventors' knowledge of falsity, Genentech cites the fact that the experiment disclosed in Example 2 of the '752 Patent was critiqued by peer reviewers when the inventors attempted to publish it. FAC ¶¶ 66-76. Reviewers for different journals on separate occasions objected that the experiments did not support the inventors' conclusion that the

[3] U Penn initially designated these datasheets as Highly Confidential and therefore sealable information. The Court does not agree that the datasheets are sealable. The datasheets reflect experiments that were conducted in the early 1990s and were either disclosed and published or closely related to other experimental data disclosed and published by U Penn.

antibody worked by down regulating p185. FAC ¶¶ 66-79. Genentech alleges that the inventors conducted additional experiments wherein transgenic mice were treated with antibody every day rather than twice a week to obtain evidence of down regulation. FAC ¶¶ 81-82. Genentech further alleges that in deposition, Dr. Katsumata admitted that these additional experiments were required to show down regulation, and that the antibody dose disclosed in the '752 Patent is insufficient to down-regulate the p185 receptor "to any measurable degree." FAC ¶¶ 78, 83-84.

c. Third Alleged Misrepresentation

Genentech alleges that the second attorney to work on the prosecution of the '752 Patent on U Penn's behalf, Dr. Mitchell Bernstein[4], misrepresented to the PTO that the '800 Application was not abandoned on March 18, 2002 when, in fact, it was abandoned on that day.

1. April 24, 2001 Final Rejection

A final rejection was issued in the '800 Application April 24, 2001. FAC ¶ 105. U Penn, through its first prosecuting attorney, Mr. DeLuca, first responded to the rejection, and then filed a Notice of Appeal, plus a request for a three-month extension of time so that the Notice of Appeal itself would be timely.[5] FAC ¶¶106-107. For "unknown reasons," the PTO did not record entry of the October 24, 2001 Notice of Appeal until January 17, 2002. FAC ¶ 109. This meant that U Penn had until March 17, 2002 to file its appeal brief. *Id*.

2. March 18, 2002 Alleged Abandonment

On January 8, 2002, Mr. DeLuca requested a one-month extension of time to file U Penn's appeal brief "from December 23, 2001 to January 23, 2002," even though the actual due date for the appeal brief was March 17, 2002. FAC ¶ 112. Also on January 8, 2002, Mr. DeLuca submitted a "Request for Continued Examination" (RCE). However, the RCE process was inapplicable to the

[4] Genentech's proposed FAC asserted that Dr. Bernstein "and/or" the previous prosecuting attorney, Mr. Mark DeLuca, committed inequitable conduct. FAC ¶ 37. Genentech stated in its Reply that it did not intend to base its inequitable conduct claim on Mr. DeLuca's actions, and that it would strike his name from FAC paragraph 37. Accordingly, the Court considers the allegations against Dr. Bernstein only. In its sur-reply, U Penn asks that factual allegations regarding Mr. DeLuca be struck from the FAC. Because these allegations form a necessary foundation for the claim against Dr. Bernstein, which the Court finds to be sufficiently pled, striking these additional allegations is not warranted.

[5] The three-month extension of time requested in October, 2001, which extended the time for U Penn to file the Notice of Appeal on October 24, 2001, was granted on January 28, 2002. FAC ¶ 110.

'800 Application. FAC ¶ 97. Mr. DeLuca did not file an appeal brief by March 17, 2002. FAC ¶¶ 97, 115, 117. Because the RCE process was not applicable to the '800 Application, Genentech asserts that U Penn's failure to file an appeal brief by March 17, 2002 resulted in abandonment of the '800 Application the following day, March 18, 2002. FAC ¶ 99.

3. February 20, 2004 Petition for Revival and Alleged Misstatements

After the alleged abandonment of the '800 Application, Dr. Bernstein took over prosecuting the Application on U Penn's behalf. On February 20, 2004, after a Notice of Allowance had issued in the '752 Patent prosecution, Dr. Bernstein submitted statements to the PTO indicating that the RCE process (initiated by Mr. DeLuca) was not applicable to the '800 Application and that he had been "informed that the ['800 application] had become abandoned for failure to file the Appeal Brief, notwithstanding the USPTO's erroneous granting of the RCE and the further prosecution and subsequent allowance of the application." FAC ¶ 122 (quoting Feb. 20, 2004 petition).

Genentech alleges that Dr. Bernstein knew that the '800 Application had been abandoned on March 18, 2002, but that he misrepresented several times that the PTO had granted a one-month extension of time to file the appeal brief, such that the due date was extended by a month to April 17, 2002. FAC ¶¶ 98, 126, 131-133. Genentech alleges that the PTO relied on these false statements regarding the date of abandonment in finding that the application became abandoned on April 18, 2002 rather than March 18, 2002. FAC ¶ 134. Genentech alleges that the difference between abandonment on March 18, 2002 versus April 18, 2002 is critical because the PTO recommenced examination of the '800 Application on April 10, 2002. FAC ¶ 135. If the '800 Application had been abandoned before April 10, 2002, Genentech alleges that the '752 Patent could not have issued. FAC ¶ 136-37.

II. Legal Standard

Pursuant to Federal Rule of Civil Procedure 15(a), a party may amend its pleading once as a matter of course within 21 days of serving it. Fed. R. Civ. Pro. 15(a)(1). After that initial period has passed, amendment is permitted only with the opposing party's written consent or leave of the court. *Id.* 15(a)(2). Rule 15 instructs that "[t]he court should freely give leave when justice so requires." *Id.* Although this rule "should be interpreted with extreme liberality, leave to amend is

not to be granted automatically." *Jackson v. Bank of Hawaii*, 902 F.2d 1385, 1387 (9th Cir. 1990) (internal citation and quotation marks omitted). Courts commonly consider four factors when determining whether to grant leave to amend: (1) bad faith on the part of the movant; (2) undue delay; (3) prejudice to the opposing party; and (4) futility of the proposed amendment. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *Lockheed Martin Corp. v. Network Solutions, Inc.*, 194 F.3d 980, 986 (9th Cir. 1999). Of these factors, prejudice to the opposing party is the most important. *Jackson*, 902 F.2d at 1387.

Under Federal Rule of Civil Procedure 9(b), "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Id.* "Inequitable conduct, while a broader concept than fraud, must be pled with particularity under Rule 9(b)." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009) (quoting *Ferguson Beauregard/Logic Controls, Div. of Dover Resources, Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003)) (quotation marks and alterations omitted).[6] As outlined in *Exergen*, the substantive elements of inequitable conduct are as follows: "(1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the PTO." *Id.* at 1327 n.3 (citing *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178, 1181 (Fed. Cir. 1995); 37 C.F.R. § 1.56 (2008)).

"[I]n pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Id.* at 1327.[7] In addition, in pleading "knowledge" and "intent,"

[6] The law of the Federal Circuit, not the law of the regional circuit, applies to the question of whether inequitable conduct has been pled in accordance with Rule 9(b). *See Exergen*, 575 F.3d at 1326 (citation omitted).

[7] Even though the court in *Exergen* did not list "why" among the questions that a pleading must answer with particularity, it did require, later in the opinion, that the pleading allege why the withheld information is material and not cumulative. 575 F.3d at 1329.

which may be averred generally under Rule 9(b), a pleading of inequitable conduct "must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Id.* at 1328-29.

III. Analysis

a. Sufficiency of Proposed Amendments

U Penn's main argument in opposing leave to amend is that the proposed amendments are not adequately pled, and that leave to amend would therefore be futile. Opp'n at 9-10. For the reasons set forth below, the Court disagrees.

1. First Alleged Misrepresentation

Genentech's allegation that the inventors presented falsified data in the '752 Patent application is sufficient to state a claim of inequitable conduct. Genentech alleges that the inventors, Drs. Greene and Katsumata, stated in Example 2 that 6 of 12 mice in the high-dose treatment group lived tumor-free for more than 90 weeks, when the data do not show that any of the mice in this group lived tumor-free for more than 86 weeks. This information was submitted to the PTO when U Penn submitted the '800 Application, which was signed by the inventors. Genentech alleges that this information would have been material to the examiner in granting the '752 Patent because the inventors frequently relied on the high-dose treatment group results to show that the patented method was effective. Accordingly, Genentech has satisfied *Exergen*'s who, what, where, when, why, and how requirements. Moreover, one can draw a reasonable inference of knowledge on the part of the inventors. Genentech alleges that the inventors "supervised" and "conducted" the experiments. FAC ¶ 47. Due to the importance of Example 2 to support the claims, it is also reasonable to infer that any falsification of the data in Example 2 was the result of intent to deceive the PTO.

U Penn argues that the data sheets Genentech cites might not be the data sheets the patent is based upon, as the original datasheets might have been lost. *See* Opp'n at 5-6. At the pleadings phase, however, the Court must take Genentech's well-pleaded allegations as true. Since U Penn

has provided the Court with no basis to discredit Genentech's allegations regarding the data sheets, it will take the allegation that this is the data summarized in Example 2 of the '752 Patent as true. If anything, U Penn's admission in its sur-reply that the datasheets show that 4 of the 6 mice died before 83 weeks of age, and that the remaining two mice lived to at least 83 and 86 weeks of age and possibly longer without visible tumors, supports the conclusion that there is a discrepancy between the datasheet and the data in Example 2, which in turn supports a reasonable inference that the data was misrepresented to the examiner. *See* Sur-reply at 5.

U Penn also argues that even if there was an error in the data reported in Example 2, Genentech has failed to allege sufficient facts establishing that a) the error would have been material to the examiner; b) that the inventors knew of this error; or c) that the inventors intended to deceive the PTO by introducing the erroneous data. None of these arguments is persuasive. Regarding materiality, Genentech alleges that Example 2 presents the only data in the '752 Patent establishing enablement (FAC ¶ 49) and that U Penn "repeatedly relied on the misrepresented data to support the pending claims" (FAC ¶ 52). These allegations are sufficient to support the conclusion that this data would have been material to the examiner's review of the claims.

Regarding the inventors' knowledge, U Penn argues that "it is not reasonable to infer that Professor Greene had knowledge about a specific set of raw data from his lab, or any alleged error in the data." This argument ignores the fact that as the named inventors, Drs. Greene and Katsumata submitted a declaration with the '800 Application stating that "I hereby state that I have reviewed and understand the contents of the ['800 Application] specification." *See* Nov. 20, 1995 Decl. at 1. In addition, Genentech has alleged that Drs. Greene and Katsumata supervised the experiment described in Example 2, and U Penn admits that this is true. U Penn argues that in their supervisory roles, the inventors were too removed from the day-to-day experiments to know about the alleged errors. *See* Opp'n at 21-22. This factual dispute is for a later stage. In light of Genentech's allegation that Drs. Greene and Katsumata supervised the experiment reported in Example 2, the Court finds that Genentech has set forth sufficient facts to lead to a reasonable inference that the named inventors of the '752 Patent knew that the data in Example 2 did not accurately reflect the results of the experiment described therein. These facts likewise support a

"plausible" and reasonable inference that the inventors misrepresented the results in Example 2 with intent to deceive. Particularly since knowledge and intent may be averred generally, Genentech has met its pleading burden.

Finally, U Penn's argument that another study conducted by Genentech corroborated Example 2 and the inventor's discovery is simply irrelevant. Opp'n at 20-21. U Penn has introduced no evidence that the inventors or the PTO relied on or even knew about the Genentech experiments they cite, which were not published until April 1, 2004 (only about a month before the '752 Patent issued), and were not cited during the '752 Patent prosecution. Genentech argues that these experiments utilized "a completely different antibody, under a different experimental protocol" to obtain "substantially different results." The Court need not resolve the factual dispute regarding this experiment now, however, as U Penn's failure to show that this evidence was considered by anyone involved in prosecuting the '752 Patent makes it irrelevant to Genentech's inequitable conduct allegations.

2. Second Alleged Misrepresentation

As a separate basis for inequitable conduct on the part of the inventors, Genentech cites U Penn's statements during prosecution that the data disclosed in the specification supported the conclusion that the claimed invention worked via "down regulation." Genentech alleges that U Penn made this amendment "specifically to overcome the PTO's rejection of a former version of claim 1 for lack of enablement" because the specification did not describe how the claimed antibodies prevented transformation of normal cells to cancer cells. FAC ¶ 59. Genentech argues that the inventors had an inadequate basis for making these statements, because the experiments disclosed in Example 2 had been criticized by other scientists for failure to demonstrate down regulation.

U Penn argues that the statements regarding down regulation that Genentech relies upon were not made by the inventors but instead by the prosecuting attorney, so that this claim fails to identify "who" made the misrepresentation. *See* Opp'n at 18-19. This argument is not well-founded. First, Genentech cites evidence from the file history showing that at least Dr. Greene made detailed statements regarding support for the "down regulation" limitation to the examiner.

Dr. Greene participated in a telephone interview with the examiner on June 14, 2001. After this telephone interview, U Penn submitted a Summary of Interview and Amendment, adding the "down regulation" limitation to the claims for the first time. *See* Aug. 24, 2001 Response and Amendment at 3-4. U Penn's summary stated that "[t]he substance of the discussion at the Examiner's Interview is reflected in the amendment of the claims and the remarks herein." U Penn also stated that during the interview, "Dr. Greene explained[] the methods of the present invention are not directed at preventing overexpression of p185 but rather the methods of the present invention *are directed at down regulating the activity of p185* " and that "[t]he data in the specification show that by down-regulating p185 activity in the mice treated with anti-p185 antibodies, the mice do not develop tumors cells while the control animals do." *Id.* (emphasis added). In the same filing, U Penn stated that "support for these amendments is found throughout the specification particularly, on page[] 14, lines 12-23." *Id*. at 4. The cited portion of the specification states that "the data indicates that continuous down-regulation of the $p185^{neuT}$ molecule leads to tumor growth suppression in a dose-dependent manner." Second, U Penn's argument that the prosecuting attorney, not the inventors, submitted the amendments to the claims and related argument is immaterial. The "knowledge and actions of applicant's attorney are chargeable to applicant." *Taltech Ltd. v. Esquel Enters.*, 604 F.3d 1324, 1334 (Fed. Cir. 2010).

U Penn also argues that Genentech has not sufficiently alleged that the statements that the specification supported the "down regulation" limitation were misrepresentations. While this is a somewhat close question, the Court finds that Genentech has pled sufficient facts to establish that the specification did not actually provide support for the "down regulation" limitation, and to support a reasonable inference that the inventors knew this. Regarding the falsity of the statements, Genentech relies in part on critiques of the inventors' research provided by third-party scientists. These critiques were provided when the inventors submitted the same experiments described in Example 2 for publication in several scientific journals. FAC ¶¶ 66, 70. As alleged by Genentech, the critiques noted that "there are no data presented showing that the monoclonal [antibody] used actually down-regulates p185 under the circumstances employed here" and that the down-regulation data was "flawed" and "difficult to interpret." FAC ¶¶ 67, 73. In response to this

criticism, the inventors conducted additional experiments using daily antibody dosing (rather than the twice-weekly dosing as in Example 2) to show that down regulation was occurring. The results were published in *Nature Medicine* in 1995. FAC ¶ 75. Genentech alleges that by conducting these experiments, the inventors "implicitly agreed" that the data reported in Example 2 did *not* adequately demonstrate down regulation. FAC ¶ 68.

Genentech also relies on deposition testimony by Dr. Katsumata, stating that he "admitted that he would need to rely on both the experiments disclosed in the patent specification and the very different down-regulation experiments in the undisclosed 1995 *Nature Medicine* publication to support the statement in the '752 Patent specification that 'the data indicates that continuous down-regulation of the $p185^{neuT}$ molecule leads to tumor growth suppression."[8] FAC ¶ 78.

If Genentech could cite only the third-party critiques of the inventors' experiments, this might not suffice to allege that the statements about support for the down regulation limitation were misrepresentations. However, Dr. Katsumata testified that "[t]o reach this conclusion [that continuous downregulation of p185 leads to tumor growth suppression] you cannot separate one experiment from another . . . this conclusion was reached based on the series of experiments we have conducted here, including two different dosage treatment groups and this particular Figure 2-A and B, particularly the . . . downregulation experiments." Thus, Dr. Katsumata admitted that the conclusion about down regulation required both the Example 2 experiment and "particularly" the follow-up experiment published in *Nature Medicine*. This testimony suggests that the inventor's statements to the examiner that "down regulation" was adequately supported by Example 2 were not accurate.

Genentech alleges that the inventors did not disclose the follow-up experiments published in Nature Medicine in 1995 "even though the results of these experiments were available to them years before the down-regulation amendment was added." FAC ¶ 77. Therefore, Genentech has sufficiently alleged that the inventors (themselves and through their counsel) misrepresented that

[8] U Penn has designated Dr. Katsumata's testimony as Highly Confidential and therefore sealable information. However, the Court does not agree that this testimony, which concerns published data, is properly sealable. Accordingly, the Court has not redacted this information from its Order, and the parties shall not redact this information from future filings in this case.

the disclosure in the patent supported adding a down regulation limitation, and that they did so in order to overcome an enablement rejection. The Court finds that Genentech has alleged sufficient facts to demonstrate the who, what, where, when, why and how of this claim. These specific factual allegations likewise support a "reasonable" inference that the misrepresentations were made knowingly and with intent to deceive. This is not the only conclusion one can draw from the facts alleged, but it is one reasonable conclusion. Genentech has therefore met its burden at the pleading stage.

3. Third Alleged Misrepresentation

Genentech's inequitable conduct claim based on the actions of Dr. Bernstein asserts that he misrepresented the procedural posture of the '800 Application (which became the '752 Patent). Because this assertion relates to a procedural rather than a substantive matter, it is somewhat distinguishable from a more typical inequitable conduct claim based on failure to disclose material prior art (such as the claim discussed in *Exergen*). However, other district courts have sustained similar claims based on the alleged misrepresentation of procedural matters to the PTO. *See Dura Operating Corp. v. Magna Int'l,* No. 10-11566, 2011 U.S. Dist. LEXIS 24485 at *9-*13 (E.D. Mich. Mar. 10, 2011). In *Dura*, the accused infringer (Magna) asserted inequitable conduct by the prosecuting attorney based on the attorney's representation to the USPTO that the application had been abandoned unintentionally. *Dura* 2011 U.S. Dist. LEXIS 24485 at *9-*13. Magna relied on evidence showing that Dura had directed that the file maintenance fee for its application not be paid, resulting in abandonment. *Id*. at *14-*15. This supported the inference that the attorney's statement that the application had not been intentionally abandoned was made without support, and with an intent to deceive the PTO. *See also Miche Bag, L.L.C. v. Marshall Group, Inc.*, No. 3:10-CV-129 RM, 2011 U.S. Dist. LEXIS 5612 at *10-*11 (Jan. 18, 2011, N.D. Ind.) (sustaining inequitable conduct claim based on alleged misrepresentation that abandonment was not intentional).

In this case, Genentech alleges that Bernstein's statements to the PTO that the '800 Application was not abandoned when U Penn failed to file an appeal on March 17, 2002 were made without support and despite significant evidence that no extension had been granted. FAC ¶¶

126, 127, 133. At the pleadings phase, the Court must take such well-pleaded facts to be true. *Lion Raisins, Inc. v. United States*, 416 F.3d 1356, 1360-61 (Fed. Cir. 2005). U Penn has provided no basis for the Court to discount Genentech's well-pleaded facts. Since the only facts before the Court at this pleadings phase show that Bernstein's statements were made without support, the Court concludes that Genentech has sufficiently alleged a false statement, by Dr. Bernstein, repeated in two submissions to the PTO on February 10, 2004 and May 10, 2004. FAC ¶¶ 125-133. In addition, Genentech alleges that the PTO relied on these statements in finding that the application became abandoned only after the PTO had resumed examination on April 10, 2002, when in fact it was abandoned before this. FAC ¶ 134. Genentech further asserts that if the application was abandoned before the PTO resumed examination, the '752 Patent could not issue, and therefore that this statement was material to patentability. FAC ¶ 137. Thus, Genentech has met the what, who, when, how, and why requirements of *Exergen*.

U Penn argues that because the PTO had the same information available to it as Bernstein, it was free to reach its own conclusions about whether or not the '800 Application was abandoned and therefore, as a matter of law, Dr. Bernstein's statements about abandonment cannot support an inequitable conduct claim. Opp'n at 13-14. However, the cases U Penn cites in support of this argument involve situations where the patentee made legal arguments distinguishing prior art that was before the examiner. *Akzo N.V. v. U.S. International Trade Com.*, 808 F.2d 1471, 1482 (Fed. Cir. 1986). In such situations, the examiner is free to draw independent conclusions about the art and the patentee's arguments about the art. The situation here is distinguishable, as it involves an alleged false statement of fact about the procedural posture of the application, rather than permissible attorney argument. Other district courts (such as the Eastern District of Michigan in the *Dura* case, discussed above) have sustained similar "procedural misrepresentation" claims in the wake of *Exergen*. Although the PTO had the same information that Dr. Bernstein had, the prosecution history was sufficiently confused to support a reasonable inference that Dr. Bernstein's representations about the extension were made with an intent to deceive the PTO. As Genentech notes, inequitable conduct can be based on misstatements of facts that are otherwise before the

examiner. *Kangaroos U.S.A. v. Caldor, Inc.*, 778 F.2d 1571, 1576 (Fed. Cir. 1985) ("[L]apse on the part of the examiner does not excuse the applicant").

In addition, Genentech has alleged sufficient facts to support the reasonable inferences that Dr. Bernstein knew his statements were false and that he intended to deceive the patent office by making them. U Penn's argument that Genentech has alleged "no facts" showing that Dr. Bernstein was aware "of facts at odds with his statements" is simply incorrect. Genentech alleges that before both submissions of the allegedly false statements, the PTO indicated that the deadline for U Penn to file its appeal was March 17, 2002. FAC ¶¶ 130, 134. Genentech also relies on Dr. Bernstein's knowledge of the file history and the rules governing patent prosecution. FAC ¶¶ 127, 132. Finally, Genentech pleads that Dr. Bernstein's statements were made with intent to deceive the patent office based on "information and belief." The inference that these statements were made with intent to deceive is "plausible" and "flows logically from the facts alleged." *Exergen*, 575 F.3d at 1329, n.5. The FAC alleges that Dr. Bernstein had a motive to deceive the PTO (because the '800 Application would otherwise have been abandoned), and that he repeated the alleged misrepresentation multiple times and in response to statements by the PTO that the appeal brief deadline was March 17, 2002. The Court finds that these facts are sufficient to support a reasonable inference that Dr. Bernstein knew the statements were false and made them with the intent to deceive the PTO. This is not the only reasonable inference that can be drawn. In light of the apparently considerable confusion on the PTO's part regarding the '800 Application prosecution, another reasonable inference flowing from the alleged facts is that Dr. Bernstein himself was simply confused about when the '800 Application was actually abandoned. However, because this is the pleadings phase, Genentech's suggested inference need not be "the single most reasonable inference" one can draw from the evidence; it need only be one (of potentially several) reasonable inferences. *Id.*

b. Timeliness of Amendment and Prejudice to U Penn

U Penn argues that Genentech improperly delayed in moving to amend, and that based on this delay and the resulting prejudice to U Penn, leave to amend should be denied. U Penn claims it will be prejudiced due to the close of fact discovery, previously set for 120 days after the claim

construction ruling (issued on May 9, 2011). However, Genentech moved to amend within the time limit set in the case schedule, and its Motion is therefore timely. In addition, the Court has now extended the case schedule, including the deadlines for fact and expert discovery, by two months pursuant to the stipulation of the parties. Accordingly, the Court finds that any prejudice to U Penn in allowing the amendment is insufficient to justify denying leave to amend.

IV. Conclusion

The Court takes no position on whether Genentech's inequitable conduct claims are likely to succeed. At the pleadings phase, the Court's role is simply to determine if the claims can go forward. As set forth above, the Court finds that Genentech has adequately pled inequitable conduct. Thus, leave to amend is GRANTED. **Genentech shall file its First Amended Complaint within 2 business days of the date of this Order.**

IT IS SO ORDERED.

Dated: May 20, 2011

LUCY H. KOH
United States District Judge